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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,542	01/18/2002	Roberto Reniero	112843-032	7122

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EXAMINER

WARE, DEBORAH K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 09/936,542	<b>Applicant(s)</b> RENIERO ET AL.	
	<b>Examiner</b> Deborah K. Ware	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-2, 4-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
       Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
       If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
       a) ☒ All    b) ☐ Some \*    c) ☐ None of:  
           1. ☒ Certified copies of the priority documents have been received.  
           2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
           3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
       \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
       a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Claims 1-2 and 4-22 are presented for reconsideration on the merits.

The amendment filed January 2, 2004, has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 4-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed January 2, 2004, have been fully considered but they are not persuasive. The deposit is noted and acknowledged, however, statement of availability as well as depository information in the specification has not been clearly set forth on the record. Thus, the rejection is reiterated below for Applicants' convenience.

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Since the microorganism and strain is newly recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. **It is noted that applicants have deposited the organism but there is no indication in the specification as to public availability.** If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

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(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807(b) which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to

obtain a sample if the test is not done by the depository; and

(7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 2 is rendered grammatically unclear for the recitation of "colonize the intestinal mucosa", and it is suggested to change "colonize" to --colonizing--.

### ***Double Patenting***

Claims 1-2 and 4-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 09/936,489. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the identical *Lactobacillus* strain for which is used in various treatments and products for purposes of alleviating diarrhea, etc., albeit a different scope wherein the copending claims do not appear to read on treating and prevention pathogenic rotoviruses. However, such pathogenic organisms are well recognized in the prior art and *Lactobacillus* strains and varied species are well known to treat and prevent pathogenic microorganisms. Therefore, one of ordinary skill in the art would have been motivated by the copending claims to provide for the claimed subject matter herein. The claims of the instant case are clearly obvious over the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2 and 4-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 & 3-23 of copending Application No. 09/936,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims

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encompass the identical *Lactobacillus* strain for which is used in various treatments and products for purposes such as treating diarrhea, et c., albeit a different scope wherein the copending claims do not appear to read on preventing colonization of the intestine with pathogenic bacteria and rotoviruses; thus, the methods and products of the instant claims are very close and similar to the copending methods and products, however, they are not identical because of a difference in their scope. However, they are very similar and one of skill would have been motivated to provide for the instant methods and products from the copending methods and products. Therefore, the instant claims are prima facie obvious over the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed January 2, 2004, have been fully considered but they are not persuasive. A terminal disclaimer is necessary since no cases have been allowed and no terminal disclaimer has been approved.

### ***Claim Rejections - 35 USC § 103***

Claims 6 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 861 905 A2, cited on the enclosed PTO-1449 Form for those reasons of record.

Claims are drawn to the *Lactobacillus paracasei* (L.p.) strain CNCM I-2116 and compositions thereof.

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EP 0 861 905 A2 teaches L. p. strains and compositions thereof. Note the abstract and page 7, all lines.

The claims differ from the EP reference cited above in that the specific strain is not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to select for various strains having similar properties and expect successful results. Clearly these L. p. strains are well known in the art for similar uses, i.e. treating diarrhea and intestinal mucosa. Thus, one of skill in the art would have been motivated to select for other strains as well. A side by side comparison of the strains would show that they possess similar if not identical properties with respect to biochemical characteristics that they have in common. The claims are prima facie obvious over the cited art.

Applicant's arguments filed January 2, 2004, have been fully considered but they are not persuasive. The arguments that the cited references fails to provide any suggestion are noted, however, the reference teaches pathogens are treated with the microorganism strains and these are well known in the art to be bacteria and viruses and the like. Viruses are agents that cause diarrhea and the disclosed compositions and strains therefore, successfully treat diarrhea as disclosed by the cited reference. Therefore, viruses and pathogenic bacteria which also cause diarrhea which is disclosed to be treated by the disclosed composition are suggested by the reference. There would be an expected successful result with the claimed strains. Therefore, in the absence of persuasive evidence and a side by side comparison the claims are



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rendered prima facie obvious. Lactobacillus strains are intrinsically capable of growth in bile salts (i.e. up to 0.4%).

***Claim Rejections - 35 USC § 102***

Claims 1-2 and 4-5, 7-17 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 861 905 A2, discussed above, for reasons of record.

Claims are directed to varied uses of Lactic acid bacteria : treating intestinal muscosa, preparing products useful for the treatment, products containing the Lactobacillus strain.

The EP is discussed above.

The claims appear to be identical to the cited disclosure and are therefore considered to be anticipated by the teachings of the cited reference. Applicant's arguments filed January 2, 2004, have been fully considered but they are not persuasive for those reasons discussed above and those of record.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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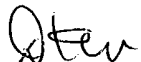
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

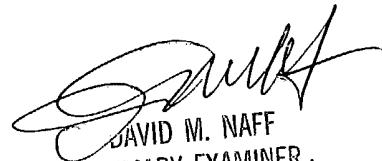
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

  
Deborah K. Ware  
March 20, 2004

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1651